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17

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/458,533	12/09/99	LI	C 99.743

HM22/0517
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EXAMINER

SISSON, B

ART UNIT	PAPER NUMBER
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1655

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DATE MAILED: 05/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/458,533

Applicant(s)

LI ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 28-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

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DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1650, Art Unit 1655, and has been assigned to Primary Examiner Bradley L. Sisson.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to an apparatus for electrical detection of molecular interactions between an immobilized probe and a target molecule, classified in class 435, subclass 287.2.

II. Claims 28-35, drawn to a method for the electrical detection of molecular interactions between an immobilized probe and a target molecule, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the apparatus as claimed can be used in materially different processes such as the detection of proteinaceous and nucleic acid-based analytes.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Kevin E. Noonan, Reg. No. 35,303, on 24 April 2000 a provisional election was made with traverse to prosecute the invention of group I, claims 1-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-35 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the apparatus of claim 2 with the added limitations of:

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- a) The apparatus further comprises at least one reference electrode that is comprised of silver/silver chloride (claims 14 and 16);
- b) The apparatus comprises an electrolyte solution of 0.1 M LiClO₄ (claim 27);
- c) There is a structural and functional relationship between the means for producing an electrical impedance and the means for detecting changes in impedance at each microelectrode in the presence of absence of a target molecule; and
- d) The target molecule is DNA that forms a duplex structure with a capture, or probe sequence, that is immobilized to the surface to the electrode;
- e) Claim 4; and
- f) The microelectrodes are made of platinum wire,

does not reasonably provide enablement for the making and use of any apparatus for electrical detection of molecular interactions between an immobilized probe and a target molecule under any type of conditions, when any type of target molecule is contemplated and when there need not be present any means for determining a reference point for such measurements. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

10. The specification has been found to provide adequate guidance for a more narrow aspect of the claimed apparatus. It is well settled that the specification must enable the full scope of the invention, not just a part of the claimed invention. Further, the specification must adequately teach not only how to make, but also how to use same. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

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“ ‘[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’).

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

11. Further, the specification must also set forth an adequate written description of the invention. In support of this position, attention is directed to the decision of *Vas-Cath inc. V. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

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This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a “written description of the invention” which is separate and distinct from the enablement requirement. The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the “applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

While the specification provides suggestions as to a variety of potential alternative embodiments, the specification, the specification has not been found to provide an adequate written description of just how these alternative embodiments are to be configured and used sans the ordinary artisan resort to undue experimentation. Clearly, if the specification does not set forth the starting materials and reaction conditions, the skilled artisans would have to resort to undue experimentation. *Genentech*. For the above reasons, and in the absence of convincing evidence to the contrary, applicant is urged to consider narrowing the scope of the claims to the embodiments adequately supported by the disclosure as outlined above.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: (a) the apparatus comprises an electrolyte solution of 0.1 M LiClO₄; there is a reference electrode present and which is comprised of silver/silver chloride; (c) there is an active, positive structural relationship between the means for producing electrical

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impedance at each microelectrode and means for detecting changes in impedance at each microelectrode; and (d) the microelectrodes comprise platinum wire.

14. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: (a) that which is needed to exist between the apparatus *per se* and means for producing electrical impedance at each microelectrode; and (b) that which is needed to exist between the apparatus and the means for detecting changes in impedance at each microelectrode.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5,312,527 (Mikkelsen et al.) discloses electrode for detecting/measuring DNA hybridization. A control, test and reference electrode are disclosed. Used an electrolyte solution as a "hybridization indicator."

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US Patent 5,776,672 (Hashimoto et al.) discloses a gene detection method which includes the use of an electrode. A variety of electrolytic solutions are disclosed. Column 25 discloses the use of either an "electrode or an optical fiber immobilized with the nucleic acid probe."

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on Monday through Thursday from between the hours of 6:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



BRADLEY L. SISSON
PRIMARY EXAMINER

GROUP 1800 1655

5/8/00